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Attorney Docket No. 21578-013

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANTS: Nathan H. Sloane

SERIAL NUMBER: 08/986,606 EXAMINER: David Lukton

FILING DATE: December 8, 1997 ART UNIT: 1653

FOR: THE USE OF THE ACTIVATED N-TERMINAL SIXTEEN AMINO ACID PEPTIDE OF THE ANTINEOPLASTIC PROTEIN (ANUP) AS A PHARMACOLOGICALLY ACTIVE ANTI-TUMOR AGENT

September 4, 2003
Boston,Massachusetts

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION OF PAUL A. DiTULLIO UNDER 37 C.F.R §1.132

I, Paul A. DiTullio, declare and state as follows:

1. I am familiar with the subject matter claimed in the above-referenced patent application.

2. I received a B.S. degree in biochemistry and a M.S. degree in cell biology from the University of Vermont.

3. I have read the Office Action mailed on April 4, 2003 and am familiar with the Examiner's grounds of rejection of the pending claims.

4. The data described herein were obtained using the methods described and claimed in the above-referenced patent application. The data presented herein

demonstrate polypeptides containing the amino acid sequence of SEQ ID NO:1 possess anti-tumor activity in animals bearing a variety of different tumor types.

5. Nude mice were were transplanted with $5x10^6$ HeLa cells (human cervical cancer), 100μL in PBS, SQ. After 3 days, tumors were measured, and treatment was initiated. Groups of mice were treated with PepA, an N-terminal ANUP polypeptide containing the amino acid sequence of SEQ ID NO:1; purified ANUP protein; or Buffer control. All peptides and the protein were diluted in buffer + 0.05%SDS followed by incubation at 37°C for 30 minutes prior to injection into the mice. Treatments were repeated three times, at days 6, 10 & 13 for a total of four treatments. Treatments were done in alternate sides of the mouse beginning with the opposite side to the tumor for all SQ injections. Both weight and tumor volume (LxWxH in mm) were measured at least 3 times per week. The experiment was completed on day 24, and the tumors were excised for weighing and histopathology after the mice were sacrificed. After 24 days of treatment, the tumors in ANUP protein group were reduced by approximately 63% of the control group, and tumors in the PepA groups were reduced by approximately 69% and 80% (500 μg and 750 μg SQ dose, respectively). The data is plotted in Figs. 1 and 2 (Appendix A and B). The data indicate that an ANUP polypeptide containing the amino acid sequence of SEQ ID NO:1 reduces tumor burden in an animal model of cervical cancer.

6. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and

further that these statements were made with the knowledge that willful false statements and the like so made are punishable by a fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date 9/4/03

Paul A. DiTullio

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